

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A23D 9/00, A23C 11/04, C11C 3/10	A1	(11) International Publication Number: WO 95/31110 (43) International Publication Date: 23 November 1995 (23.11.95)
(21) International Application Number: PCT/US95/05930 (22) International Filing Date: 11 May 1995 (11.05.95) (30) Priority Data: 08/242,763 13 May 1994 (13.05.94) US (71) Applicant: AMERICAN HOME PRODUCTS CORPORATION [US/US]; Five Giralda Farms, Madison, NJ 07940-0874 (US). (72) Inventors: LIEN, Eric, Louis; 1 Anthony Drive, Malvern, PA 19355 (US). TOMARELLI, Rudolph, Michael; 850 Wynonah Drive, Auburn, PA 17922 (US). (74) Agents: ALICE, Ronald, W.; American Home Products Corporation, Five Giralda Farms, Madison, NJ 07940-0874 (US) et al.	(81) Designated States: AM, AU, BB, BG, BR, BY, CA, CN, CZ, EE, FI, GE, HU, IS, JP, KG, KP, KR, KZ, LK, LR, LT, LV, MD, MG, MN, MX, NO, NZ, PL, RO, RU, SE, SG, SI, SK, TJ, TM, TT, UA, UG, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(54) Title: CORANDOMIZED FAT COMPOSITIONS FOR INFANT FORMULAS (57) Abstract <p>The invention disclosed herein comprises fat compositions primarily for use in nutritionally complete infant formulas in which the constituent palmitic acid oils and oleic acid oils are corandomized. The invention additionally includes such corandomized fat compositions with medium-chain triglycerides added, particularly for use in nutritional products for preterm or low birthweight infants. The corandomization of the palmitic acid oil and oleic acid oil yields a mixture of triglycerides having a substantially different chemical makeup than that of the native oils themselves, than the native oils when randomized individually, or than palmitic and lauric acids corandomized. The corandomization affords an economical means of providing a very highly absorbed fat composition and in particular results in a considerable reduction in the excretion, i.e. non-absorption, of palmitic acid.</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

CORANDOMIZED FAT COMPOSITIONS
FOR INFANT FORMULAS

5 The invention disclosed herein comprises fat compositions primarily for use in
nutritionally complete infant formulas in which the constituent palmitic acid oils and
oleic acid oils are corandomized. The invention additionally includes such
corandomized fat compositions with medium-chain triglycerides added, particularly
for use in nutritional products for preterm or low birthweight infants. Such
10 corandomization of two or more oils yields a mixture of triglycerides having a
substantially different chemical makeup than that of the native oils themselves or than
the native oils when randomized individually. Corandomization of the palmitic acid
and the oleic acid oils affords an economical means of providing a very highly
absorbed fat composition with a fatty acid profile approaching that of human milk.

15 **Background Of The Invention**

U.S. Patent No. 3,542,560, issued on November 24, 1970 to Tomarelli et al.,
discloses fat compositions for infant formulas having an increased portion of the
palmitic acid in the beta (2) position of the triglyceride. This increase is obtained by
20 blending lard, or a synthetic beta-monopalmitin, with the other oils comprising the fat
composition, which have a relatively low portion of beta palmitic acid. Such other
oils listed are corn, soy bean, palm, peanut, coconut, olive, babassu, cotton seed, oleo,
and tallow. However, the use of lard is unacceptable in many areas of the world for
religious reasons, and synthetic triglycerides are prohibitively expensive for large
25 scale use. Thus, fat compositions for use in infant formulas are sought which are
broadly acceptable on religious dietary grounds, are highly absorbed, have a fatty acid
content similar to human milk and are economical to manufacture on very large
scales.

Three more recent U.S. patents disclose all vegetable oil fat compositions for
30 use in infant nutritional products with palm oil as the sole palmitic acid oil. These
are U.S. Patent No. 4,282,265, issued on August 4, 1981, to Theuer and U.S. Patent
Nos. 4,614,663 and 4,721,626, issued on September 30, 1986 and January 26, 1988,
respectively, to Rule.

Most recently, European patent publication No. 0376628, published on July 4,
35 1990, to American Home Products Corporation (Tomarelli) discloses all vegetable oil
fat compositions in which the palmitic acid oil alone is randomized. This European
patent publication also discloses all vegetable oil fat compositions including medium-

-2-

chain triglycerides for use in infant nutritional products for preterm or low birthweight infants in which the palmitic acid oil alone is randomized. EP 0488800 discloses fat compositions differing from those of EP 0376628 in that at least one palmitic acid oil and one lauric acid oil are corandomized. Corandomization of these oils causes interesterification randomly between the fatty acids of the palmitic acid oil and the lauric acid oil. This corandomization of the two oils resulted in surprisingly superior absorbability to that found when only the palm olein oil of the mixture was randomized.

The present invention differs in that at least one palmitic acid oil and at least one oleic acid oil are corandomized. In consequence a fat blend with surprisingly superior absorbability and a close simulation to human breast milk can be prepared. Advantageously, the use of canola oil provides a relatively high level of α -linolenic acid which is converted to docohexaenoic acid (DHA) in the infant body.

Palmitic acid and stearic acid are the fatty acids most poorly absorbed, i.e. most readily excreted, during infant nutrition. Where the fat blend of an infant formula is made from oils of vegetable origin, the content of stearic acid in the fat blend is relatively small. Thus palmitic acid represents the important poorly absorbed fatty acid. Hence reduction in the amount of excretion of palmitic acid constitutes a desirable target in the art. Corandomization of a palmitic acid oil with either a lauric acid oil or an oleic acid oil reduces the proportion of palmitic acid excreted compared with the corresponding mixture not subjected to corandomization. It has been discovered that the reduction is greater in the case of the corandomization product used in the invention compared with the corandomization product used in EP 0488800. That discovery is an advantage of the invention.

This invention provides a fat composition particularly for use in a nutritionally complete infant formula, comprising

- (a) 16-32%, calculated on the weight of the fat composition, of one or more lauric acid oils selected from coconut oil, babassu oil, and palm kernel oil;
- (b) 20-49%, calculated on the weight of the fat composition, of one or more palmitic acid oils selected from palm oil, and palm olein oil;
- (c) 13-37%, calculated on the weight of the fat composition, of one or more oleic acid oils selected from olive oil, safflower oleic oil, sunflower oleic oil, and canola oil; and
- (d) 0-32%, calculated on the weight of the fat composition, of one or more linoleic acid oils selected from corn oil, cottonseed oil, safflower oil, soybean oil, and sunflower oil,

-3-

wherein the palmitic acid oil or oils and the oleic acid oil or oils, and optionally the linoleic acid oil or oils, are corandomized, the amounts of the oils being such that the fat composition contains, per 100 parts by weight of the total fatty acids present as triglycerides,

- 5 (i) 9-22 parts of lauric acid;
 (ii) 13-22 parts of palmitic acid;
 (iii) 28-43 parts of oleic acid; and
 (iv) 10-23 parts of linoleic acid.

We shall refer to such compositions as corandomized fat compositions.

- 10 Preferred corandomized fat compositions of this aspect of the invention are those wherein only the palmitic acid oil or oils and oleic acid oil or oils are corandomized. ~~Also preferred are those fat compositions wherein only one oil of~~ each type is used, and only one palmitic acid oil and one oleic acid oil are corandomized. The preferred palmitic acid oil is palm olein oil. The preferred oleic acid oil is canola oil. The preferred linoleic acid oils are corn oil and soybean oil, of which soybean oil is particularly preferred. It will be appreciated that the three oleic acid oils, canola, safflower oleic, and sunflower oleic oil, have sufficiently high linoleic acid contents (20 and 15 percent, respectively) and therefore a linoleic acid oil may not be needed to provide the desired nutritional amounts of linoleic acid.
- 15 Most advantageously, the use of canola oil provides a relatively high level of α -linolenic acid which is converted to docohexaenoic acid (DHA) in the infant body. DHA is present in human milk, but is itself not a constituent of available vegetable oils. DHA is of crucial importance to retinal function. Advantageous linoleic acid to α -linolenic acid ratios of 15 to 1 to 4 to 1 (more preferably 11 to 1 to 4 to 1) are obtained from this aspect of the invention. Preferably the corandomized fat compositions of the invention have 0.9-3.7 parts of α -linolenic acid per 100 parts by weight of the total fatty acids present as triglycerides. More preferably this amount is 1.2-3.7, advantageously 2.4-3.7, parts of α -linolenic acid. The stearic acid content may be 2.8-4.0, preferably 2.9-3.4, parts per 100 parts of fatty acids.

- 20 Preferred corandomized fat compositions of the invention comprise
- 25 (a) 16-27%, calculated on the weight of the fat composition, of a lauric acid oil selected from coconut oil, babassu oil, and palm kernel oil;
- (b) 30-46%, calculated on the weight of the fat composition, of a palmitic acid oil selected from palm oil and palm olein oil;
- 30 (c) 13-34%, calculated on the weight of the fat composition, of one or two oleic acid oils selected from olive oil, safflower oleic oil, sunflower oleic oil, and canola oil; and

-4-

(d) 7-26%, calculated on the weight of the fat composition, of a linoleic acid oil selected from corn oil, cottonseed oil, safflower oil, soybean oil, and sunflower oil,

wherein the palmitic acid oil and the oleic acid oil or oils are corandomized,

5 the amounts of the oils being such that the fat composition contains, per 100 parts by weight of the total fatty acids present as triglycerides,

- (i) 9-15 parts of lauric acid;
- (ii) 16-22 parts of palmitic acid;
- (iii) 32-42 parts of oleic acid; and
- 10 (iv) 10-20 parts of linoleic acid.

Preferably the corandomized fat compositions of the invention have 1.2-3.7 parts of α -linolenic acid per 100 parts by weight of the total fatty acids present as triglycerides. More preferably this amount is 2.4-3.7 parts of α -linolenic acid.

Linoleic acid to α -linolenic acid ratios of 11 to 1 to 4 to 1 are preferred.

15 Especially preferred corandomized fat compositions of the invention are those wherein the oils comprise

- (a) 20-25% coconut oil;
- (b) 39-46% palm oil or palm olein oil;
- (c) 14-29% canola oil; and
- 20 (d) 11-20% corn oil or soybean oil,

wherein the palm oil or palm olein oil and the canola oil are corandomized, and wherein the fat composition contains, per 100 parts by weight of total fatty acid present as triglycerides,

- (i) 9-14 parts of lauric acid;
- 25 (ii) 18-22 parts of palmitic acid;
- (iii) 33-39 parts of oleic acid;
- (iv) 15-19 parts of linoleic acid; and
- (v) 2.4-3.7 parts of α -linolenic acid.

Linoleic acid to α -linolenic acid ratios of 11 to 1 to 4 to 1 are preferred.

30 Further particularly preferred corandomized fat compositions of the invention are those wherein the ratio of the palmitic acid oil to the oleic acid oil is between 78/22 palmitic acid oil/oleic acid oil and 50/50 palmitic acid oil/oleic acid oil. Especially preferred are fat compositions of the invention wherein the ratio of the palmitic acid oil to the oleic acid oil is between 75/25 palmitic acid oil/oleic acid oil and 55/45 palmitic acid oil/oleic acid oil. The use of canola oil as the oleic acid oil
35 to be corandomized with the palmitic acid oil is further advantageous because it

-5-

reduces the lauric acid content of the resulting fat composition to an amount somewhat closer to that of human milk. (Compare Table IIIa with Table V.)

In a further advantageous aspect, this invention also provides a fat composition particularly for use in a nutritionally complete preterm (or low birthweight) infant formula, comprising

- (a) 8-27%, calculated on the weight of the fat composition, of one or more lauric acid oils selected from coconut oil, babassu oil, and palm kernel oil;
- (b) 10-49%, calculated on the weight of the fat composition, of one or more palmitic oils selected from palm oil or palm olein oil;
- (c) 8-45%, calculated on the weight of the fat composition, of one or more oleic acid oils selected from olive oil, safflower oleic oil, sunflower oleic oil, and canola oil;
- (d) 0-22%, calculated on the weight of the fat composition, of one or more linoleic acid oils selected from corn oil, cottonseed oil, safflower oil, soybean oil, and sunflower oil; and
- (e) 10-50%, calculated on the weight of the fat composition, of medium-chain triglycerides (MCT's),

wherein the palmitic acid oil or oils and the oleic acid oil or oils, and optionally the linoleic acid oil or oils, are corandomized, the amounts of the oils being such that the fat composition contains, per 100 parts by weight of the total fatty acids present as triglycerides,

- (i) 8-34 parts of caprylic acid;
- (ii) 4-16 parts of capric acid;
- (iii) 5-15 parts of palmitic acid;
- (iv) 16-39 parts of oleic acid; and
- (v) 9-20 parts of linoleic acid.

We shall refer to such compositions as corandomized, preterm fat compositions.

Preferred corandomized, preterm fat compositions of the invention are those wherein only the palmitic acid oils and the oleic acid oils are corandomized. Also preferred are those preterm fat compositions wherein only one oil of each type is used, and only one palmitic acid oil and one oleic acid oil are corandomized. The preferred palmitic acid oil is palm olein oil. The preferred lauric acid oil is coconut oil. The preferred oleic acid oil is canola oil, and the preferred linoleic acid oils are corn oil and soybean oil. As noted above, canola oil, safflower oil and sunflower oleic oil, independently, may provide sufficient levels of linoleic acid such that no

linoleic acid oil is needed in some of the subject preterm fat compositions. Preferably the corandomized fat compositions of the invention have 1.1-3.7 parts of α -linolenic acid per 100 parts by weight of the total fatty acids present as triglycerides. More preferably this amount is 1.4-3.7 parts of α -linolenic acid, most preferably 2.3-3.7 parts of α -linolenic acid. Advantageous linoleic acid to α -linolenic acid ratios of 15 to 1 to 4 to 1 (more preferably 11 to 1 to 4 to 1) are obtained from this aspect of the invention.

Preferred corandomized, preterm fat compositions of the invention comprise

- (a) 9-27 %, calculated on the weight of the fat composition, of a lauric acid oil selected from coconut oil, babassu oil, and palm kernel oil;
- (b) 15-40 %, calculated on the weight of the fat composition, of a palmitic oil selected from palm oil, or palm olein oil;
- (c) 12-33 %, calculated on the weight of the fat composition, of one or two oleic acid oils selected from olive oil, safflower oleic oil, sunflower oleic oil, and canola oil;
- (d) 8-22%, calculated on the weight of the fat composition, of a linoleic acid oil selected from corn oil, cottonseed oil, safflower oil, soybean oil, and sunflower oil; and
- (e) 10-30%, calculated on the weight of the fat composition, of medium-chain triglycerides (MCT's),

wherein the palmitic acid oil and the oleic acid oil are corandomized, the amounts of the oils being such that the fat composition contains, per 100 parts by weight of the total fatty acids present as triglycerides,

- (i) 8-22 parts of caprylic acid;
- (ii) 4-10 parts of capric acid;
- (iii) 9-19 parts of palmitic acid;
- (iv) 23-36 parts of oleic acid; and
- (v) 13-19 parts of linoleic acid.

Preferably the corandomized fat compositions of the invention have 1.4-3.7 parts of α -linolenic acid per 100 parts by weight of the total fatty acids present as triglycerides. More preferably this amount is 2.3-3.7 parts of α -linolenic acid.

Especially preferred preterm, corandomized fat compositions of the invention are those wherein the oils comprise

- (a) 9-27% coconut oil;
- (b) 16-32% palm oil or palm olein oil;
- (c) 16-33% canola oil;
- (d) 9-20% corn oil or soybean oil; and

-7-

- (e) 10-30% MCT's,
wherein the palm olein oil and the canola oil are corandomized,
and wherein the fat composition contains, per 100 parts by weight of total fatty acid
present as triglycerides,
- 5 (i) 8-21 parts of caprylic acid;
 (ii) 4-10 parts of capric acid;
 (iii) 10-17 parts of palmitic acid;
 (iv) 27-33 parts of oleic acid;
 (v) 14-18 parts of linoleic acid; and
10 (vii) 2.3-3.4 parts of α -linolenic acid.

Further particularly preferred corandomized fat compositions of the invention
~~are those wherein the ratio of the palmitic acid oil to the oleic acid oil is between~~
78/22 palmitic acid oil/oleic acid oil and 25/75 palmitic acid oil/oleic acid oil.
Especially preferred are fat compositions of the invention wherein the ratio of the
15 palmitic acid oil to the oleic acid oil is between 65/35 palmitic acid oil/oleic acid oil
and 35/65 palmitic acid oil/oleic acid oil.

Thus, in general this invention provides a fat composition useful for the
nutrition of a human infant, the fat composition comprising

20 (a) one or more lauric acid oils selected from coconut oil, babassu oil, and palm
kernel oil;
 (b) one or more palmitic acid oils selected from palm oil, and palm olein oil;
 (c) one or more oleic acid oils selected from olive oil, safflower oleic oil, sunflower
oleic oil, and canola oil;
 (d) optionally one or more linoleic acid oils selected from corn oil, cottonseed oil,
25 safflower oil, soybean oil, and sunflower oil, and
 (e) optionally, medium chain triglycerides
wherein the palmitic acid oil or oils and the oleic acid oil or oils, and, optionally the
linoleic acid oil or oils, are corandomized, the amounts of the oils being such that the
fatty acid composition is nutritionally adapted to the human infant. The foregoing
30 descriptions of the invention represent preferred aspects of the invention for regular
term infants and preterm (low birthweight) infants.

The corandomization products of the palmitic acid oil or oils and the oleic
acid oil or oils as used in the present invention are mixtures of triglycerides having
unique chemical structures. In native fats and oils, the various fatty acids are
35 positioned, i.e. esterified, on one of the three hydroxy groups of the glycerol molecule
in an ordered pattern that is characteristic of the particular fat or oil. In general, the
long chain saturated fatty acids, C16-C18, are predominantly on the 1 and 3 position,

-8-

the mono and polyunsaturated fatty acids on the 2 or middle position of the triglyceride molecule. A second distributional characteristic of the fatty acids on the glycerol backbone that exists in nature results in a very large percentage of the triglycerides being so-called mixed triglycerides, i.e. each of the three fatty acids, or at least two, are different. There is only a small amount of simple triglycerides, those in which the three hydroxy groups are esterified with the same fatty acids, e.g. tripalmitin (C16), triolein (C18), etc.

Chemical interesterification, also called randomization (since it alters the non-random distribution of nature), may be accomplished by heating the fat or oil for a short period of time, usually with a catalyst such as sodium methylate. The fatty acids leave their natural position on the triglyceride and rearrange in a random fashion, i.e., equally on each of the three positions. Thus, one-third of each individual fatty acid is on the one position, one-third on the two, and one-third on the three position of the triglycerides. Randomization of an individual native fatty acid oil also results in an increase in the content of simple triglycerides, or in the case of a palmitic acid oil, of triglycerides consisting only of the long chain saturated fatty acids palmitic and stearic acids. For example, when palm oil or palm olein oil is randomized alone, there is an increase in the amount of palmitic-stearic triglycerides from approximately 3% in the native oils to 11% in the individually randomized oils. Such long chain, completely saturated triglycerides are particularly poorly absorbed. Further, the resulting corandomization product of the palmitic acid oil or oils and oleic acid oil or oils differs chemically from those in which the palmitic acid oil or oils and the lauric acid oil or oils are corandomized.

The effect of corandomization on the positional distribution of fatty acids of native palm olein and canola oils is presented in Table IIa.

Table IIa
Effect Of Corandomization On The Positional Distribution
Of The Fatty Acids

5	Fatty acid**	<u>Non-randomized</u> <u>65% PO/35% Can*</u>		<u>Corandomized</u> <u>65% PO/35% Can*</u>	
		<u>%</u> <u>FA</u>	<u>% in</u> <u>2-pos.</u>	<u>%</u> <u>FA</u>	<u>% in</u> <u>2-pos.</u>
10	C12	0.2	-	0.2	33
	C14	0.7	7	0.7	34
	C16	27.5	6	27.8	33
	C18	3.5	44	3.6	32
15	C18:1	46.5	8	46.1	33
	C18:2	14.1	49	13.8	33

* PO = palm olein oil and Can = canola oil

** See Table IV for the names of the fatty acids

20

Corandomized palm olein and oleic acid oil also differs importantly in its biochemical properties from a mixture of native palm olein and oleic acid oils. This difference is particularly significant for use in infant nutritional products. In the digestion of triglycerides in the intestine, pancreatic lipase hydrolyzes the fatty acids at the 1 and 3 position, resulting in two free fatty acids and a 2-monoglyceride containing the fatty acid of the glyceride 2 position. A long chain saturated fatty acid is less well absorbed as a free fatty acid than if it is present in the gut as a 2-monoglyceride.

Palmitic acid is the major saturated fatty acid of human milk triglycerides. It is a long chain, C16, fatty acid. Long chain fatty acids are not as well absorbed as short chain or unsaturated fatty acids, yet the palmitic acid of human milk is well absorbed because the palmitic acid of human milk is predominantly in the 2-position, and, after intestinal digestion, the majority of the palmitic acid is present in the intestine as the more readily absorbed 2-monopalmitin.

As seen in Table IIa above, corandomized palm olein oil/canola oil has triple the amount of palmitic acid in the 2 position of the triglyceride as does the respective mixture of native palm olein oil and native canola oil. Accordingly, the nutritional value of the corandomized fat compositions of the invention is significantly improved

-10-

with respect to prior all vegetable oil fat compositions which use only the native palmitic acid oils.

Corandomization may be accomplished by heating from 0.5 to 4 hours, preferably 0.5 to 2 hours, at temperatures from 100-140°C, preferably 110-130°C, with 0.05-0.50 percent, preferably 0.05-0.15 percent, of sodium methylate present. The end point of the corandomization process should provide palmitic acid at least 27%, and preferably 33%, in the 2 position of the triglycerides.

The present invention also provides a nutritionally complete food product adapted for human infant nutrition containing the fat compositions according to the invention, as fully described above. Such food product comprises the fat composition, a protein source, a carbohydrate source, and appropriate levels of vitamins, minerals and other nutritional factors. The product may be a ready-to-feed liquid, or in the form of a powder or concentrated liquid adapted to provide a ready-to-feed form by the addition of water and stirring. The product preferably contains 2.2 to 4.0 g, advantageously about 3.6 g of a fat composition of the invention; 1.2 to 3.0 g, advantageously about 1.5 g of protein; and 6 to 9 g of carbohydrate - per 100 ml of the ready-to-feed liquid formula supplying preferably 60-75 kcal per 100 ml.

As protein sources there may be mentioned casein, salts of casein (e.g. potassium caseinate), whey protein concentrate, soybean protein isolate, cow's milk protein, or hydrolyzed whey, casein or soy protein. Cow's milk protein differs from that of human milk in the proportions present as casein and whey protein. Cow's milk has about 80% casein and 20% whey proteins, whereas human milk has about 40% casein and about 60% whey proteins. Accordingly, the protein used may be adapted to simulate that of human milk by supplementing cow's milk protein with an appropriate amount of whey protein. Because whey contains a very high proportion of the minerals of milk, the whey is subjected to demineralization, in particular by electrodialysis or ultrafiltration, to prepare whey protein. When a milk-free diet for infants who are intolerant of cow's milk protein is desired, the protein source may be isolated soy protein or hydrolyzed casein or whey protein. The proteins may be used in combination.

As a carbohydrate source lactose is generally preferred in formulas for normal, healthy infants. However, lactose would be contraindicated for infants suffering from galactosemia, lactose intolerance, or cow's milk protein intolerance. (In the latter case, the lactose may contain traces of cow's milk protein.) Where a milk-free diet is desired, the carbohydrate source may be sucrose, corn syrup solids (glucose polymers), or a combination of corn syrup solids with sucrose. The carbohydrates may also be used in combination.

-11-

Additionally, the food product (infant formula) would contain nutritionally acceptable quantities of the following minerals and vitamins: calcium, phosphorus, potassium, sodium, chloride, magnesium, iron, copper, zinc, manganese, iodine and selenium; and vitamin A, vitamin D, vitamin E, vitamin K₁, vitamin B₁, vitamin B₂,
5 vitamin B₆, vitamin B₁₂, vitamin C, pantothenic acid, niacin, folic acid, biotin, choline and inositol. The food product could contain other nutritional factors, such as taurine, carnitine, nucleotides, and a source of long chain polyunsaturated fatty acids.

The present invention also provides a nutritionally complete food product adapted for the feeding of preterm or low birthweight infants, said product containing
10 a fat composition according to the invention as fully described above. The product may be a ready-to-feed liquid or a powder or a concentrated liquid adapted to provide the ready-to-feed form by the addition of water and stirring. The product preferably contains, per 100 ml of ready-to-feed formula, 1.5 - 2.5 g of protein, preferably 2.0 - 2.2 g of whey predominant protein; 2.2 - 6.0 g of fat, preferably 3.5 - 4.4 g of the
15 preferred corandomized fat blend of the present invention; and 4.7 - 11.0 g of carbohydrate, preferably 7.0 - 8.6 g consisting of approximately equal parts of lactose and glucose polymers, said amounts supplying preferably 65 - 85 kcal / 100ml. Additionally, the preterm food product contains the vitamins, minerals and other nutritional factors described above for the term formula, but in amounts suitable for
20 the preterm or low birthweight infant.

The invention includes a process for the preparation of the fat composition by blending the components (a), (b), (c), and (d) [and (e) for the preterm fat composition] together in such proportions that the resultant composition has the required composition of fatty acids. Additionally, an emulsifying agent such as lecithin or
25 diglycerides, in an amount up to 2 percent of the total weight of the fat composition, may be blended into the fat mixture. Soy bean lecithin concentrate is commonly used, and since the concentrate contains essentially the same amount of fatty acids as in soybean oil, in the examples of fat blends presented below, 1 percent of soybean lecithin concentrate is included in the listed amounts of soybean oil. The proportions
30 of the oils to be used can be calculated from the fatty acid profiles of the individual oil components. The blending is preferably performed at a blending temperature above the melting point of the fat mixture, whereby each component oil is in the liquid phase. The heating of the oils to the blending temperature and the mixing of the oils in a conventional mixing apparatus should be carried out with careful
35 temperature control. A blending temperature within the range of about 36°C to 50°C may be used. Oil soluble vitamins are normally dissolved in the fat composition as a preliminary step.

-12-

To prepare the nutritionally complete food product, the completed fat mixture is mixed with the other components which have been separately combined. The combination is then emulsified. Processing to a final ready-to-feed liquid, concentrated liquid or powder may be carried out in a conventional manner.

5 More particularly, this invention includes a process for preparing a fat composition particularly useful in a nutritionally complete infant formula, said process being characterized in that the corandomization product obtainable by interesterification of one or more palmitic acid oils and one or more oleic acid oils and optionally one or more linoleic acid oils, which oils and their relative proportions are set out respectively in (b), (c) and (d) below, until the palmitic acid of the product
10 random triglycerides is at least 27 % in the 2-position, is admixed with one or more lauric acid oils and optionally one or more linoleic acid oils, which oils and their relative proportions are set out respectively in (a) and (d) below,

15 wherein the resulting fat composition comprises,

- (a) 16-32%, calculated on the weight of the fat composition, of one or more lauric acid oils selected from coconut oil, babassu oil, and palm kernel oil;
- (b) 20-49%, calculated on the weight of the fat composition, of one or
20 more palmitic acid oils selected from palm oil, and palm olein oil;
- (c) 13-37%, calculated on the weight of the fat composition, of one or more oleic acid oils selected from olive oil, safflower oleic oil, sunflower oleic oil, and canola oil; and
- (d) 0-32%, calculated on the weight of the fat composition, of one or
25 more linoleic acid oils selected from corn oil, cottonseed oil, safflower oil, soybean oil, and sunflower oil,

the amounts of the oils being such that the fat composition contains, per 100 parts by weight of the total fatty acids present as triglycerides,

- (i) 9-22 parts of lauric acid;
- (ii) 13-22 parts of palmitic acid;
- (iii) 28-43 parts of oleic acid and
- (iv) 10-23 parts of linoleic acid.

30

Also included is a process for making a nutritionally complete food product adapted for human infant nutrition, said process characterized in that a protein source,
35 a carbohydrate source, vitamins, minerals, and a fat composition made by the above-stated process are admixed.

-13-

Additionally, this invention includes a process for preparing a fat composition particularly useful in a nutritionally complete infant formula for preterm infants, said process being characterized in that the corandomization product obtainable by interesterification of one or more palmitic acid oils and one or more oleic acid oils and optionally one or more linoleic acid oils, which oils and their relative proportions are set out respectively in (b), (c) and (d) below, until the palmitic acid of the product random triglycerides is at least 27 % in the 2-position, is admixed with one or more lauric acid oils and medium-chain triglycerides and optionally one or more linoleic acid oils, which oils and their relative proportions are set out respectively in (a), (e) and (d) below, wherein the resulting fat composition comprises,

- (a) 8-27%, calculated on the weight of the fat composition, of one or more lauric acid oils selected from coconut oil, babassu oil, and palm kernel oil;
 - (b) 10-49%, calculated on the weight of the fat composition, of one or more palmitic oils selected from palm oil or palm olein oil;
 - (c) 8-45%, calculated on the weight of the fat composition, of one or more oleic acid oils selected from olive oil, safflower oleic oil, sunflower oleic oil, and canola oil;
 - (d) 0-22%, calculated on the weight of the fat composition, of one or more linoleic acid oils selected from corn oil, cottonseed oil, safflower oil, soybean oil, and sunflower oil; and
 - (e) 10-50%, calculated on the weight of the fat composition, of medium-chain triglycerides,
- the amounts of the oils being such that the fat composition contains, per 100 parts by weight of the total fatty acids present as triglycerides,
- (i) 8-34 parts of caprylic acid;
 - (ii) 4-16 parts of capric acid;
 - (iii) 5-15 parts of palmitic acid;
 - (iv) 16-39 parts of oleic acid; and
 - (v) 9-20 parts of linoleic acid.

Also included is a process for making a nutritionally complete food product adapted for human infant nutrition, said process characterized in that a protein source, a carbohydrate source, vitamins, minerals, and a fat composition for preterm infants made by the above-stated process are admixed.

The practice of the invention is further represented by the following examples:

-14-

Example 1**Vegetable Oil Fat Blends Containing A Corandomization Product
Of Palmitic Acid And Oleic Acid Oils**

- 5 Table IIIb below shows the fatty acid composition of three preferred vegetable oil fat blends of the invention in which palm olein and canola oil are corandomized.

Table IIIa**Preferred Vegetable Oil Fat Blends****10 Containing A Corandomization Product Of Palm Olein and Canola Oil**

		<u>R1</u>	<u>R2</u>	<u>R3</u>
		<u>PO/C</u>	<u>PO/C</u>	<u>PO/C</u>
	<u>Oils</u>	<u>63/37</u>	<u>63/37</u>	<u>75/25</u>
15	Coconut	22.0	22.0	22.0
	Palm olein*	41.0*	41.0*	45.0*
	Canola*	24.0*	24.0*	15.0*
	Corn	13.0	-	-
	Soybean	-	13.0	18.0
20	<u>fatty acids**</u>			
	C8	1.5	1.5	1.5
	C10	1.1	1.1	1.1
	C12	12.0	12.0	12.0
	C14	4.3	4.3	4.3
25	C16	19.5	19.4	21.1
	C18	3.0	3.2	3.4
	C16:1	0.2	0.2	0.2
	C18:1	37.5	37.1	34.6
	C18:2	16.9	16.5	17.9
30	<u>C18:3</u>	<u>2.4</u>	<u>3.0</u>	<u>2.5</u>

* Oils corandomized

** See Table IV for the names of the fatty acids.

PO = palm olein oil and C = canola oil

-15-

Table IIIb below shows the fatty acid composition of six vegetable oil fat blends of the invention in which the palmitic acid oil and one or two oleic acid oils are corandomized.

Table IIIb
Vegetable Oil Fat Blends
Containing A Corandomization Product Of Palmitic Acid and Oleic Acid Oils

		<u>R4</u>	<u>R5</u>	<u>R6</u>	<u>R7</u>	<u>R8</u>	<u>R9</u>	<u>R10</u>
	<u>Lauric acid oils</u>							
10	coconut	25		25			20	25
	babassu		25		25			
	palm kernel					25		
	<u>Palmitic acid oils*</u>							
	palm olein	32*	32*			32*	30*	32*
15	palm			32*	32*			
	<u>Oleic acid oils*</u>							
	safflower oleic	28*	28*			28*		23*
	canola			28*	28*			5*
	sunflower oleic						28*	
20	<u>Linoleic acid oils</u>							
	soy	15	15			15	22	15
	safflower			15	15			
	<u>Fatty acids**</u>							
25	C12	13.6	11.4	13.5	11.3	12.9	10.9	13.6
	C14	4.8	4.8	4.8	4.8	5.0	3.8	4.8
	C16	17.0	17.0	18.1	18.1	17.3	16.2	16.9
	C18	3.0	3.5	3.3	3.8	3.0	3.8	3.0
	C18:1	40.6	42.7	32.5	34.6	42.8	42.4	39.8
30	C18:2	16.0	16.0	21.7	21.7	16.3	18.4	16.3
	C18:3	0.9	0.9	2.3	2.3	0.9	1.4	1.4

* oils corandomized

** See Table V for the names of the fatty acids

35

-16-

Table IVa below shows the fatty acid composition of three preferred preterm vegetable oil fat blends of the invention in which palm olein and canola oil are corandomized.

5

Table IVaPreferred Preterm Vegetable Oil Fat BlendsContaining A Corandomization Product Of Palm Olein and Canola Oil

10		<u>P1</u> <u>35/65</u>	<u>P2</u> <u>45/55</u>	<u>P3</u> <u>63/37</u>
	<u>Oils</u>			
	Coconut	9.0	27.0	27.0
	Palm Olein*	18.0*	20.0*	30.0*
	Canola*	33.0*	24.0*	18.0*
15	Corn	10.0	19.0	-
	Soy	-	-	15.0
	MCT	30.0	10.0	10.0
	<u>Fatty acids**</u>			
20	C6	0.7	0.2	0.2
	C8	20.4	8.5	8.5
	C10	9.7	4.4	4.4
	C12	5.3	14.7	14.8
	C14	1.8	4.9	5.0
25	C16	9.8	12.3	15.5
	C18	1.8	2.3	2.8
	C16:1	0.1	0.1	0.1
	C18:1	31.4	30.3	29.4
	C18:2	14.5	18.1	15.2
30	C18:3	3.2	2.5	2.6

* oils corandomized

** See Table V for the names of the fatty acids

Table IVb below shows the fatty acid composition of five preterm vegetable oil fat blends of the invention in which the palmitic acid oil and one or two oleic acid oils are corandomized.

		<u>Table IVb</u>				
		<u>Preterm Vegetable Oil Fat Blends</u>				
		<u>Containing A Corandomization Product Of Palmitic Acid and Oleic Acid Oils</u>				
		<u>P4</u>	<u>P5</u>	<u>P6</u>	<u>P7</u>	<u>P8</u>
5						
10	<u>Lauric acid oil</u>					
	Coconut	27	-	27	27	27
	Palm kernel	-	27	-	-	-
15	<u>Palmitic acid oil*</u>					
	Palm olein	20*	20*	20*	20*	20*
	<u>Oleic acid oil*</u>					
	High oleic safflower	25*	25*	-	-	20*
	High oleic sunflower	-	-	-	25*	-
20	Canola	-	-	-	24*	5*
	<u>Lnoleic acid oil</u>					
	Corn	-	-	-	19	-
	Soy	18	18	18	-	18
25	<u>Medium-chain tri.</u>					
	MCT	10	10	10	10	10
30	<u>Fatty acids**</u>					
	C8	8.5	7.0	8.5	8.5	8.5
	C10	4.4	3.9	4.4	4.4	4.4
	C12	14.8	14.0	14.8	14.8	14.8
	C14	5.0	5.2	4.9	5.0	5.0
	C16	12.6	13.0	12.4	15.5	12.5
35	C18	2.6	2.5	3.0	2.8	2.6
	18:1	33.9	36.3	35.0	29.4	33.2
	18:2	15.9	16.2	14.8	15.2	16.2
	18:3	1.1	1.1	1.1	2.6	1.6
40						

* oils corandomized

** See Table V for the names of the fatty acids

-18-

Table V below shows the ranges of the fatty acid composition of human milk. These ranges were taken from 11 published reports from the U.S., Great Britain, Canada, West Germany, Australia and Finland from 1965-1983. Further variances from these ranges will be found in other geographic areas, for example, where the diet is largely vegetarian or where fish or other seafoods are a major food source. The fat compositions of the invention have a fatty acid pattern reasonably similar to that of human milk.

Table VHuman Milk Fatty Acid Ranges

10

15

20

<u>Fatty Acid</u>	<u>Ranges Reported</u>
C8 Caprylic	0.1
C10 Capric	0.8 - 1.6
C12 Lauric	3.1 - 6.3
C14 Myristic	5.1 - 7.4
C16 Palmitic	20.2 - 25.2
C18 Stearic	5.5 - 10.4
C16:1 Palmitoleic	3.7 - 4.1
C18:1 Oleic	29.4 - 46.9
C18:2 Linoleic	7.2 - 15.6
C18:3 Linolenic	0.7 - 2.0

Example 2

The excretion data given below was obtained on young male rats according to the method described in U.S. Patent No. 3,542,560, issued on November 24, 1970, to Tomarelli et al., under "Part II" of the Example, at column 4, lines 34-73. Despite the fact that the rat absorbs fats very efficiently, marked differences in the fecal excretion of fat due to corandomization are readily demonstrated.

Table VIa shows the reduction in excretion of the total fatty acids and of the palmitic acid itself from a diet containing corandomized palm olein-canola oil compared to one containing the same ratio of nonrandomized palm olein and canola oils.

15

Table VIa

Fat Excretion Of Mixtures Of Native Palm Olein and Canola Oils
Versus That Of Corandomized Palm Olein-Canola Oil

20

Ratio
PO/Can

Native
Oils

Corand.
Oil

Native
Oils

Corand.
Oil

----- Percent Excretion -----

25

----- Total Fatty Acids -----

----- Palmitic Acid -----

75/25

10.3 ± 0.55

2.66 ± 0.15

22.9 ± 1.29

5.48 ± 0.26

65/35

5.50 ± 0.32

1.74 ± 0.27

14.3 ± 0.70

3.58 ± 0.58

55/45

4.28 ± 0.25

1.62 ± 0.10

11.1 ± 0.62

3.34 ± 0.22

30

all differences are statistically significant

In the following Table VIb the results in respect of palmitic acid excretion from Table VIa are compared with those given in EP 0488800 in respect of corandomization products of palm olein oil and coconut oil.

Table VIb

Palmitic Acid Excretion Of Corandomization Products Versus
That From Non-randomized Oil Blends

5

10

15

Composition Of Corandomization Product and Non-Randomized Oil Blend		Ratio of Percentage Excretion of Palmitic Acid From Blend of Oils To That From Its Corandomization Product	
% by weight <u>Palm Olein Oil</u>	% by weight <u>Other Oil</u>	Other Oil	
		<u>Coconut Oil</u>	<u>Canola Oil</u>
75	25	1.87	4.18
65	35	3.69	3.99
55	45	-	3.32
56	44	2.49	-

- 20 The results given in Table VIb show that corandomization of palm olein oil with canola oil has a greater effect on reducing the excretion of palmitic acid than corandomization of the palm olein oil with coconut oil.

Example 3

25

30

Given below are three examples of the composition of a complete infant nutritional food product using a corandomized fat composition of the invention. In the examples, the preferred fat composition is used, but any corandomized palmitic acid oil-oleic acid oil fat blend of the invention may be used. ("PO" below stands for palm olein oil, "S-Oleic" stands for safflower oleic oil, and "Can." stands for Canola oil.)

Example 3 - Regular Term Formulas

	<u>1A</u> non-fat milk and demineralized whey	<u>1B</u> soy protein isolate	<u>1C</u> nonfat milk + demineralized whey
5	Protein		
	<u>R2</u> Coco.-22% PO*.41% Can.*-24% Soy-13%	<u>R2</u> Coco.-22% PO*.41% Can.*-24% Soy-13%	<u>R3</u> Coco.-22% PO*.45% Can.*-15% Soy-18
10	Fat (oils)**		
	Carbohydrate		
15	<u>Constituents</u>	<u>per liter</u>	<u>per liter</u>
	Energy kcal	676	all
	Protein g	15	as for 1A
	Fat g	36	
20	Carbohydrate g	72	
	Water g	904	
	Linoleic Acid mg	3300	
	Vitamin A IU	2000	
	Vitamin D IU	400	
25	Vitamin E IU	9.5	
	Vitamin K mcg	55	
	Thiamin (Vit B1) mcg	670	
	Riboflavin (Vit B2) mcg	1000	
	Vitamin B6 mcg	420	
30	Vitamin B12 mcg	1.3	
	Niacin mcg	5000	
	Folic Acid (Folacin) mcg	50	
	Pantothenic Acid mcg	2100	
	Biotin mcg	15	
35	Vit C (Ascorbic Acid) mg	55	
	Choline mg	100	
	Inositol mg	32	
	Taurine mg	40	
	Carnitine mg	37	
40	Nucleotide monophosphates mg	29.5	
	Calcium mg	420	
	Phosphorus mg	280	
	Magnesium mg	45	
	Iron mg (w/wo)	12.0/1.5	
45	Zinc mg	5	
	Manganese mcg	150	
	Copper mg	470	
	Iodine mcg	60	
	Sodium mg	150	
50	Potassium mg	560	
	Chloride mg	375	

* oils corandomized

****see Table IIIa for fatty acid content**

-22-

Example 4

Given below are two examples of the composition of a complete preterm infant nutritional food product using a corandomized preterm fat composition according to the invention. In the examples, the preferred preterm fat composition is used, but any corandomized palmitic acid oil / lauric acid oil fat composition of the invention may be used. ("PO" below stands for palm olein oil, and "MCT" stands for medium-chain triglycerides.)

Example 4 - Preterm Formulas

10

Protein	<u>2A</u> non-fat milk and deminer- alized whey	<u>2B</u> non-fat milk and deminer- alized whey	<u>2C</u> Nnfat mlk + deminer- ized whey
15			
Fat (oils)**	<u>P3</u> MCT-10% PO*-30% Can.*-18% Coco.-27% Soy-15%	<u>P2</u> MCT-10% PO*-20% Can.*-24% Coco.-27% Corn-19%	<u>P3</u> MCT-10% PO*-30% Can.*-18% Coco.-27% Soy-15%
20			
Carbohydrate	lactose and glucose polymers	lactose and glucose polymers	lactose + glucose polymers
25			
<u>Constituents</u>	<u>per liter</u>	<u>per liter</u>	<u>per liter</u>
30			
Energy kcal	810	810	all as for 2A
Protein g	20	22.0	
Fat g	44	42.1	
Carbohydrate g	86	86.5	
Water g	880	882	
Linoleic Acid mg	4000	4050	
35			
Vitamin A IU	2400	8100	
Vitamin D IU	480	2430	
Vitamin E IU	15	36.5	
Vitamin K mcg	70	105	
Thiamin (Vit B1) mcg	800	2025	
40			
Riboflavin (Vit B2) mcg	1300	2835	
Vitamin B6 mcg	500	2025	
Vitamin B12 mcg	2	3.2	
Niacin mcg	6300	36450	
Folic Acid (Folacin) mcg	100	284	
45			
Pantothenic Acid mcg	3600	12150	
Biotin mcg	18	16.2	
Vit C (Ascorbic Acid) mg	70	284	
Choline mg	127	64.8	
Inositol mg	32	200	

Example 4 - Preterm Formulas (continued)

5

	<u>Constituents</u>	<u>2A</u> per liter	<u>2B</u> per liter	<u>2C</u> per liter
10	Taurine mg	48	48	
	Carnitine mg	49	59	
	Nucleotide monophosphates mg	29.5	29.5	all
	Calcium mg	750	1000	as for 2A
	Phosphorus mg	400	600	
15	Magnesium mg	70	81	
	Iron mg	3	2.4	
	Zinc mg	8	10.5	
	Manganese mcg	200	105	
	Copper mcg	700	1417.5	
20	Iodine mcg	83	81	
	Sodium mg	320	405	
	Potassium mg	750	972	
	Chloride mg	530	729	
25	* oils corandomized **see Table IVa for fatty acid content			

CLAIMS

1. A fat composition useful for the nutrition of a human infant, the fat composition comprising

- 5 (a) 16-32%, calculated on the weight of the fat composition, of one or more lauric acid oils selected from coconut oil, babassu oil, and palm kernel oil;
- (b) 20-49%, calculated on the weight of the fat composition, of one or more palmitic acid oils selected from palm oil, and palm olein oil;
- 10 (c) 13-37%, calculated on the weight of the fat composition, of one or more oleic acid oils selected from olive oil, safflower oleic oil, sunflower oleic oil, and canola oil; and
- (d) 0-32%, calculated on the weight of the fat composition, of one or more linoleic acid oils selected from corn oil, cottonseed oil, safflower oil, soybean oil, and sunflower oil,
- 15 wherein the palmitic acid oil or oils and the oleic acid oil or oils, and optionally the linoleic acid oil or oils, are corandomized, the amounts of the oils being such that the fat composition contains, per 100 parts by weight of the total fatty acids present as triglycerides,
- 20 (i) 9-22 parts of lauric acid;
- (ii) 13-22 parts of palmitic acid;
- (iii) 28-43 parts of oleic acid and
- (iv) 10-23 parts of linoleic acid.

2. A fat composition according to claim 1, containing, per 100 parts by weight of the total fatty acids present as triglycerides, 1.2-3.7 parts of α -linolenic acid.

25

3. A fat composition according to claim 1 or 2, which comprises
- (a) 16-27%, calculated on the weight of the fat composition, of a lauric acid oil selected from coconut oil, babassu oil, and palm kernel oil;
- (b) 30-46%, calculated on the weight of the fat composition, of a palmitic acid oil selected from palm oil and palm olein oil;
- 30 (c) 13-34%, calculated on the weight of the fat composition, of one or two oleic acid oils selected from olive oil, safflower oleic oil, sunflower oleic oil, and canola oil; and
- (d) 7-26%, calculated on the weight of the fat composition, of a linoleic acid oil selected from corn oil, cottonseed oil, safflower oil, soybean oil, and sunflower oil,
- 35

wherein the palmitic acid oil and the oleic acid oil or oils are corandomized,

-25-

the amounts of the oils being such that the fat composition contains, per 100 parts by weight of the total fatty acids present as triglycerides,

- 5 (i) 9-15 parts of lauric acid;
(ii) 16-22 parts of palmitic acid;
(iii) 28-43 parts of oleic acid and
(iv) 10-23 parts of linoleic acid.

4. A fat composition as claimed in any one of claims 1 to 3, containing, per 100 parts by weight of the total fatty acids present as triglycerides, 2.4-3.7 parts of α -
10 linolenic acid.

5. A fat composition according to any one of claims 1 or 4, wherein only the palmitic acid oil or oils and the oleic acid oil or oils are corandomized.

6. A fat composition according to claim 5, wherein only one palmitic acid oil and one oleic acid oil are corandomized.

15 7. A fat composition according to claim 6, wherein the palmitic acid oil is palm olein oil and the oleic acid oil is canola oil.

8. A fat composition according to any one of claims 1 to 6, wherein one palmitic acid oil is used, which is palm olein oil.

20 9. A fat composition according to any one of claims 1 to 6, wherein one oleic acid oil is used, which is canola oil.

10. A fat composition according to any one of claims 1 to 9, wherein only one of each kind of oil is used.

11. A fat composition according to any one of claims 1 to 10, wherein only one linoleic acid oil is used, which is corn oil or soybean oil.

25 12. A fat composition according to any one of claims 1 to 11, wherein the linoleic acid to α -linolenic acid ratio is between 15 to 1 and 4 to 1.

13. A fat composition according to claim 12, wherein the linoleic acid to α -linolenic acid ratio is between 11 to 1 and 4 to 1.

30 14. A fat composition according to claim 1, which comprises

- (a) 20-25% coconut oil;
(b) 39-46% palm oil or palm olein oil;
(c) 14-29% canola oil; and
(d) 11-20% corn oil or soybean oil,

wherein the palm olein oil and the canola oil are corandomized,
35 and wherein the fat composition contains, per 100 parts by weight of total fatty acid present as triglycerides,

-26-

- (i) 9-14 parts of lauric acid;
- (ii) 18-22 parts of palmitic acid;
- (iii) 33-39 parts of oleic acid;
- (iv) 15-19 parts of linoleic acid; and
- (v) 2.4-3.7 parts of α -linolenic acid.

15. A nutritionally complete food product adapted for human infant nutrition, comprising a protein source, a carbohydrate source, vitamins, minerals, and a fat composition as claimed in any one of claims 1 to 14.

16. A fat composition useful for the nutrition of a preterm infant or low birth weight infant, the fat composition comprising

(a) 8-27%, calculated on the weight of the fat composition, of one or more lauric acid oils selected from coconut oil, babassu oil, and palm kernel oil;

(b) 10-49%, calculated on the weight of the fat composition, of one or more palmitic oils selected from palm oil or palm olein oil;

(c) 8-45%, calculated on the weight of the fat composition, of one or more oleic acid oils selected from olive oil, safflower oleic oil, sunflower oleic oil, and canola oil;

(d) 0-22%, calculated on the weight of the fat composition, of one or more linoleic acid oils selected from corn oil, cottonseed oil, safflower oil, soybean oil, and sunflower oil; and

(e) 10-50%, calculated on the weight of the fat composition, of medium-chain triglycerides,

wherein the palmitic acid oil or oils and the oleic acid oil or oils, and optionally the linoleic acid oil or oils, are corandomized, the amounts of the oils being corandomized, the amounts of the oils being such that the fat composition contains, per 100 parts by weight of the total fatty acids present as triglycerides,

- (i) 8-34 parts of caprylic acid;
- (ii) 4-16 parts of capric acid;
- (iii) 5-15 parts of palmitic acid;
- (iv) 16-39 parts of oleic acid; and
- (v) 9-20 parts of linoleic acid

17. A fat composition according to claim 16, which contains, per 100 parts by weight of the total fatty acids present as triglycerides, 1.4-3.7 parts of α -linolenic acid.

-27-

18. A fat composition according to claim 17, which comprises
- (a) 9-27 %, calculated on the weight of the fat composition, of a lauric acid oil selected from coconut oil, babassu oil, and palm kernel oil;
 - (b) 15-40 %, calculated on the weight of the fat composition, of a palmitic oil selected from palm oil, or palm olein oil;
 - (c) 12-33 %, calculated on the weight of the fat composition, of one or two oleic acid oils selected from olive oil, safflower oleic oil, sunflower oleic oil, and canola oil;
 - (d) 8-22%, calculated on the weight of the fat composition, of a linoleic acid oil selected from corn oil, cottonseed oil, safflower oil, soybean oil, and sunflower oil; and
 - (e) 10-30%, calculated on the weight of the fat composition, of medium-chain triglycerides,
- wherein the palmitic acid oil and the oleic acid oil are corandomized,
- the amounts of the oils being such that the fat composition contains, per 100 parts by weight of the total fatty acids present as triglycerides,
- (i) 8-22 parts of caprylic acid;
 - (ii) 4-10 parts of capric acid;
 - (iii) 9-19 parts of palmitic acid;
 - (iv) 23-36 parts of oleic acid; and
 - (v) 13-19 parts of linoleic acid.
19. A fat composition according to any one of claims 16 to 18, which contains, per 100 parts by weight of the total fatty acids present as triglycerides, 2.3-3.4 parts of α -linolenic acid.
20. A fat composition according to any one of claims 16 or 19, wherein only the palmitic acid oil or oils and the oleic acid oil or oils are corandomized.
21. A fat composition according to claim 20, wherein only one palmitic acid oil and one oleic acid oil are corandomized.
22. A fat composition according to claim 21, wherein the palmitic acid oil is palm olein oil and the oleic acid oil is canola oil.
23. A fat composition according to any one of claims 16 to 21, wherein the palmitic acid oil is palm olein oil.
24. A fat composition according to any one of claims 16 to 21 and 23, wherein one oleic acid oil is used, which is canola oil.
25. A fat composition according to any one of claims 16 to 24, wherein only one linoleic acid oil is used, which is corn oil or soybean oil.

-28-

26. A fat composition according to any one of claims 16 to 25, wherein the linoleic acid to α -linolenic acid ratio is between 15 to 1 and 4 to 1.

27. A fat composition according to claim 26, wherein the linoleic acid to α -linolenic acid ratio is between 11 to 1 and 4 to 1.

5 28. A fat composition as claimed in claim 16, wherein the oils comprise

- (a) 9-27% coconut oil;
- (b) 16-32% palm oil or palm olein oil;
- (c) 16-33% canola oil;
- (d) 9-20% corn oil or soybean oil; and
- 10 (e) 10-30% medium chain triglycerides,

wherein the palm olein oil and the canola oil are corandomized,

and wherein the fat composition contains, per 100 parts by weight of total fatty acid present as triglycerides,

- (i) 8-21 parts of caprylic acid;
- 15 (ii) 4-10 parts of capric acid;
- (iii) 10-17 parts of palmitic acid;
- (iv) 27-33 parts of oleic acid;
- (v) 14-18 parts of linoleic acid; and
- (vii) 2.3-3.4 parts of α -linolenic acid.

20 29. A nutritionally complete food product adapted for the nutrition of preterm or low birthweight human infants, which product comprises a protein source, a carbohydrate source, vitamins, minerals and a fat composition as claimed in any one of claims 16 to 28.

25 30. A process for preparing a fat composition particularly useful in a nutritionally complete infant formula, said process being characterized in that the corandomization product obtainable by interesterification of one or more palmitic acid oils and one or more oleic acid oils and optionally one or more linoleic acid oils, which oils and their relative proportions are set out respectively in (b), (c) and (d) below, until the palmitic acid of the product random triglycerides is at least 27 % in
30 the 2-position,
is admixed with one or more lauric acid oils and optionally one or more linoleic acid oils, which oils and their relative proportions are set out respectively in (a) and (d) below,

wherein the resulting fat composition comprises,

- 35 (a) 16-32%, calculated on the weight of the fat composition, of one or more lauric acid oils selected from coconut oil, babassu oil, and palm kernel oil;

(b) 20-49%, calculated on the weight of the fat composition, of one or more palmitic acid oils selected from palm oil, and palm olein oil;

(c) 13-37%, calculated on the weight of the fat composition, of one or more oleic acid oils selected from olive oil, safflower oleic oil, sunflower oleic oil, and canola oil; and

(d) 0-32%, calculated on the weight of the fat composition, of one or more linoleic acid oils selected from corn oil, cottonseed oil, safflower oil, soybean oil, and sunflower oil,

the amounts of the oils being such that the fat composition contains, per 100 parts by weight of the total fatty acids present as triglycerides,

(i) 9-22 parts of lauric acid;

~~(ii) 13-22 parts of palmitic acid;~~

(iii) 28-43 parts of oleic acid and

(iv) 10-23 parts of linoleic acid.

31. A process according to claim 30, in which the fat composition contains, per 100 parts by weight of the total fatty acids present as triglycerides, 1.2-3.7 parts of α -linolenic acid.

32. A process for making a nutritionally complete food product adapted for human infant nutrition, said process characterized in that a protein source, a carbohydrate source, vitamins, minerals, and a fat composition made by a process as claimed in any one of claims 30 and 31 are admixed.

33. A process for preparing a fat composition particularly useful in a nutritionally complete infant formula for preterm infants, said process being characterized in that the corandomization product obtainable by interesterification of one or more palmitic acid oils and one or more oleic acid oils and optionally one or more linoleic acid oils, which oils and their relative proportions are set out respectively in (b), (c) and (d) below, until the palmitic acid of the product random triglycerides is at least 27 % in the 2-position, is admixed with one or more lauric acid oils and medium-chain triglycerides and optionally one or more linoleic acid oils, which oils and their relative proportions are set out respectively in (a), (e) and (d) below, wherein the resulting fat composition comprises,

(a) 8-27%, calculated on the weight of the fat composition, of one or more lauric acid oils selected from coconut oil, babassu oil, and palm kernel oil;

(b) 10-49%, calculated on the weight of the fat composition, of one or more palmitic oils selected from palm oil or palm olein oil;

-30-

(c) 8-45%, calculated on the weight of the fat composition, of one or more oleic acid oils selected from olive oil, safflower oleic oil, sunflower oleic oil, and canola oil;

5

(d) 0-22%, calculated on the weight of the fat composition, of one or more linoleic acid oils selected from corn oil, cottonseed oil, safflower oil, soybean oil, and sunflower oil; and

(e) 10-50%, calculated on the weight of the fat composition, of medium-chain triglycerides,

10

the amounts of the oils being such that the fat composition contains, per 100 parts by weight of the total fatty acids present as triglycerides,

(i) 8-34 parts of caprylic acid;

(ii) 4-16 parts of capric acid;

(iii) 5-15 parts of palmitic acid;

(iv) 16-39 parts of oleic acid; and

15

(v) 9-20 parts of linoleic acid.

34. A process according to claim 33, in which the fat composition contains, per 100 parts by weight of the total fatty acids present as triglycerides, 1.4-3.7 parts of α -linolenic acid.

20

35. A process for making a nutritionally complete food product adapted for human infant nutrition, said process characterized in that a protein source, a carbohydrate source, vitamins, minerals, and a fat composition made by a process as claimed in any one of claims 33 and 34 are admixed.

INTERNATIONAL SEARCH REPORT

Inter. Appl. Application No
PCT/US 95/05930

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A23D9/00 A23C11/04 C11C3/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A23D A23C C11C A23L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 496 456 (UNILEVER) 29 July 1992 see the whole document	1-29
Y	---	30-35
Y	EP,A,0 209 327 (UNILEVER) 21 January 1987 see page 4, line 30 - page 5, line 7 ---	30-35
A	PATENT ABSTRACTS OF JAPAN vol. 11 no. 43 (C-402) ,7 February 1987 & JP,A,61 209544 (UEDA SEIYU KK) 17 September 1986, see abstract --- -/--	1

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

* & * document member of the same patent family

Date of the actual completion of the international search

31 August 1995

Date of mailing of the international search report

14.09.95

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Dekeirel, M

Internal Application No
PCT/US 95/05930

Inter.	nal Application No
--------	--------------------

PCT/US 95/05930

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DATABASE WPI Week 9019 Derwent Publications Ltd., London, GB; AN 90-145197 & JP,A,02 092 997 (FUJI OIL KK) , 3 April 1990 see abstract ---	1
A	GB,A,2 250 299 (THE NISSHIN OIL MILLS) 3 June 1992 see claims 1-8 ---	1
P,A	WO,A,94 26855 (LODERS-CROKLAAN) 24 November 1994 see claims 1-15 -----	1-35

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. Application No

PCT/US 95/05930

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
✓ EP-A-496456	29-07-92	AT-T- 119744 AU-B- 640301 AU-A- 1034492 DE-D- 69201651 DE-T- 69201651 ES-T- 2069961 JP-A- 5076283 ZA-A- 9200474	15-04-95 19-08-93 06-08-92 20-04-95 13-07-95 16-05-95 30-03-93 23-07-93
EP-A-209327	21-01-87	GB-A- 2178752 AU-B- 586264 AU-A- 6011686 CA-A- 1297336 JP-B- 4041599 JP-A- 62025936 SE-A- 8603100 US-A- 4876107	18-02-87 06-07-89 15-01-87 17-03-92 08-07-92 03-02-87 13-01-87 24-10-89
GB-A-2250299	03-06-92	JP-A- 4197188 JP-B- 6087787 DE-A- 4125415 US-A- 5183675	16-07-92 09-11-94 04-06-92 02-02-93
WO-A-9426855	24-11-94	AU-B- 6721794	12-12-94